



EC CERTIFICATE

Certificate No 718/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

SIEM - NOVA SRL

20089 ROZZANO (MI) - VIA VARALLI 1 (ITA) - Italy

manages in the factory of:

20089 ROZZANO (MI) - VIA VARALLI 1 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Surgical aspirators

Aerosoltherapy equipment

Ultrasonic aerosoltherapy equipment

Surgical aspirator for centralized vacuum

Surgical smoke filtrations

Suction Filter

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AE00026; 10AF00108; 10AG00067; 10EK00040; 10EO00008; DM16-0004030-01; DM18-0028030-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2004-02-23
 Updated: 2019-02-07
 Substitution Date: 2017-01-19
 Expiry Date: 2024-02-06



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Annex

Surgical aspirators

Type ref. 6110-A1 CURET-MAX; 6110-A1 LIPO-MAX; 6110-A1 MAX; 6110-A2 CURET-SPEEDY; 6110-A2 LIPO-SPEEDY; 6110-A2 SPEEDY; 6110-A3 SIEM; 6110-A4 LIPO-JUNIOR; 6110-A4 JUNIOR; 6110-A5 GASTRO-EVER; 6110-A6 GASTRO-JUNIOR; 6110-A7 GASTRO-PLEURICO-TORACICO; 6110-A8 PLEURICO-TORACICO; 6110-A9 VENTOSA-MAX; 6110-A10 VENTOSA-SIEM; DOMI AC; DOMI DC.

Aerosoltherapy equipment

Type ref. 1001 AS UNO; 1001 AS UNO R.

Ultrasonic aerosoltherapy equipment

Type ref. 1001 NEB.

Surgical aspirator for centralized vacuum

Type ref. 6110 A1 CENTRAL MAX; 6110 A3 CENTRAL SIEM; 6110 A4 CENTRAL JUNIOR; 6110 A5 CENTRAL GASTRO; 6110 A6 CENTRAL GASTRO JUNIOR; 6110 A7 CENTRAL GASTRO PLEURICO TORACICO; 6110 A8 CENTRAL PLEURICO TORACICO.

Surgical smoke filtrations

Type ref. FILTRUM; SMOKE BUSTER.

Suction Filter

Series: 6000 Type ref. SUCTION FILTER.

Series: 7000 Type ref. VENT FILTER.

Series: 8000 Type ref. SMOKE FILTER.

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